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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

WARE, DEBORAH K

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,533

Applicant(s)

O'SULLIVAN, DANIEL J.

Examiner

Deborah K. Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 41-58 are presented for reconsideration on the merits.

Response to Amendment

The amendment filed June 28, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The issue under 35 USC 112, second paragraph has been removed based on Applicant's arguments.

Specification

Applicant's updated status of the parent case 09/884,894, now U.S. Patent No. 6,746,672, as provided by their amendment to the specification is appreciated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Art Unit: 1651

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 41-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Masuyama et al, cited on enclosed PTO-892 Form.

Claims are drawn to composition comprising Bifidobacterium and milk product and method for administering it to a human or animal. The composition can be in the form of a tablet or capsule. The composition comprises an iron chelator.

Masuyama et al teach composition comprising Bifidobacterium, note column 2, line 61, and milk product, note also lines 45-50. and method for administering it to a human or animal, note column 4, lines 10-11. The composition can be in the form of a tablet or capsule, note column 4, lines 8-9. The composition comprises an iron chelator, note column 3, lines 66-67 wherein vitamin and minerals as well as protein are disclosed to be present. Minerals such as cobalt and magnesium function as iron chelators.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings therein.

Response to Arguments

Applicant's arguments filed June 28, 2006, have been fully considered but they are not persuasive. First, the argument that the claims do not include an iron chelator is noted, however, Applicant's claim 47 and 58 clearly set forth and recite "an iron chelator". Therefore, the characterization of the claims in the action of March 28, 2006, is true. Albeit the iron chelator is in a dependent claim and not required by the

Art Unit: 1651

independent claims when the independent claims stand on their own, however, it is required by the dependent claims 47 and 58. The Examiner is required to address the limitations of each claim whether it be an independent claim or dependent claim.

Second, the argument that no iron chelator is explicitly taught by the cited reference is noted, however, minerals (i.e. Mg) can function as iron chelators, and their presence is disclosed by Masuyama et al. (note col. 3, line 67). Furthermore, from Applicant's first argument it is Applicant's characterization that the claims do not require an iron chelator so the criticality of the optional presence of such an element is not of particular importance to the claimed subject matter.

In addition, Applicant argues that fermentation by a lactic acid bacterium or a lactic acid bacterium and a yeast taught by Matsuyama et al, will lower pH and iron is soluble at a low pH and hence non-limiting because acid conditions will remove iron from chelators. However, Matsuyama et al teach the identical microorganism for which to include with a food product as claimed herein and Applicant's claimed product and method do not render microbial growth non-limiting. Therefore, since the identical composition and method are disclosed then the iron status of Matsuyama et al can not be construed as being limiting for microbial growth.

Also, Applicant has requested documentary evidence that supports minerals, such as magnesium, can function as iron chelators. As provided on the PTO-892 Form, Grossmith (US Patent NO. 3,200,136) teach at column 3, lines 19-22, and column 5, line 35, and column 6, lines 62-75; hence the use of iron in combination with magnesium can function as an iron chelator. Metal chelates derived from minerals,

Art Unit: 1651

such as magnesium, are well known. Iron and magnesium complexed together will provide for iron but not in its free form because it forms a chelate with minerals, such as magnesium.

Therefore, the claims drawn to an iron chelator and substantially no free iron being present are inherent to the cited disclosure, Matsuyama et al. Furthermore, the argument that Matsuyama et al do not expressly teach that when cultured in a medium comprising at least about 0.3 mM 2,2'-dipyridyl, secretes a siderophore, and wherein the siderophore inhibits growth of *Lactococcus lactis*, is noted, however, by Applicant's own admission in their instant response of June 28, 2006, at page 6 of 11, the claims do not require this limitation and hence the art is not required to expressly teach what is not required by the claims. However, the identical microorganism is disclosed and will, therefore, inherently possess the capability of producing a siderophore under these conditions.

The Matsuyama et al reference clearly teach the same microorganism *Bifidobacterium* combined with a food and it will inherently produce a siderophore under appropriate conditions. Applicants have shown no difference between the claimed microorganism or the disclosed microorganism. Further, the siderophore is not even required by the claims as admitted by Applicant. Also the reference is silent with respect to the presence of free iron and hence the conditions of high iron must not be required by Matsuyama et al. Therefore, the rejection is sustained.

Double Patenting

Art Unit: 1651

Upon reconsideration of the parent's restriction requirement, the following double patenting is deemed necessary because the restriction requirement of July 2, 2002, of the parent case 09/884,894, does not include a group drawn to a composition containing a Bifidobacterium and food, this subject matter was added later by an amendment in the parent case and so the subject matter was not addressed in the restriction requirement, hence the rejection is as follows:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41 and 47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,746,672. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims only differ from claim 3 in terms of scope.

Art Unit: 1651

Claims are drawn to a composition comprising Bifidobacterium and either a food or a beverage, and no free iron, comprising an iron chelator or combination thereof.

Claim 3 is drawn to a composition comprising Bifidobacterium and either a food or a beverage, and no free iron, comprising an iron chelator or combination thereof.

The instantly filed claims are obvious over the claim 3 because although there is a difference in scope of the claimed subject matter the composition itself comprises the same elements as to render one obvious over the other. One of skill would have been motivated to provide for the claimed composition based upon a reading of the claim 3 of U.S. Patent No. 6,746,672. Hence the claims are obvious over the cited claim 3 of the U.S. Patent No. 6,746,672.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 are cited as documentary evidence and to show the state of the art, respectively.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


DEBORAH K. WARE
PATENT EXAMINER
Deborah K. Ware
September 16, 2006